



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1504]

Independent Assessment of the Process for the Review of Device Submissions; Final Comprehensive Findings and Recommendations and First Implementation Plan; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled "Independent Assessment of the Process for the Review of Device Submissions; Final Comprehensive Findings and Recommendations and First Implementation Plan" that appeared in the Federal Register of May 29, 2014 (79 FR 30853). The document announced Booz Allen Hamilton's final comprehensive findings and recommendations submitted as part of their independent assessment of the process for the review of medical device submissions as well as FDA's first implementation plan based on Booz Allen Hamilton's high priority recommendations issued December 11, 2013. The notice was issued earlier than intended. The documents will be available on June 11, 2014, as required by the Medical Device User Fee Amendments of 2012 (MDUFA) III Performance Goals and Procedures Commitment Letter.

FOR FURTHER INFORMATION CONTACT: Amber Sligar, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm 3291, Silver Spring, MD 20993-0002, 301-796-9384, Amber.Sligar@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of Thursday, May 29, 2014, in FR Doc. 2014-12403, on pages 30853-30854, the following correction is made:

The notice implied that Booz Allen Hamilton's final comprehensive findings and recommendations and FDA's first implementation plan are available as of May 29, 2014. In fact, the documents will be available Wednesday, June 11, 2014, at the following Web site:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAlI/ucm314036.htm>.

Dated: June 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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